REMARKS

Claims 2-19 and 22-31 were pending in the subject application, with claims 2-10, and 12-19 withdrawn from consideration. Applicants have herein canceled claims 2-10, 12-19, and 22 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in the future, amended claim 11 to recite the dosage range recited by now canceled claim 22, and amended claim 24 to be consistent with amended claim 11.

The amendments to the claims introduce no new matter. Accordingly, applicants respectfully request entry of this Amendment. Upon entry of this Amendment, claims 11 and 23-31, as amended, will be pending and under examination in the subject application.

Claims Rejected Under 35 U.S.C. § 103(a)

The Examiner rejected claims 11 and 22-31 under 35 U.S.C. 103(a) as being unpatentable over Bar-Tana (U.S. Patent No. 4,689,344).

The Examiner asserted that Bar-Tana teaches a method of treating hypercholesterolemia and hypertriglyceridemia in *Psamomys Obesus* comprising the administration of 3,3,14,14 tetramethyl hexadecane 1,16 dioic acid ("M16"). The Examiner further asserted that Bar-Tana teaches that the daily dosage will depend on the age, needs, and tolerance of the individual patient, but it will usually range from 50 mg to 5,000 mg per day.

The Examiner acknowledged that Bar-Tana does not teach the dose range "from about 30 mg per day to about 400 mg per day" recited in claim 11 or the dose ranges recited in claims 22-24.

The Examiner then asserted that the dosage range taught by Bar-Tana of 50 to 5,000 mg per day clearly overlaps with the dosages of the instant claims. The Examiner cited M.P.E.P. 2144.05 which states "in the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists." The Examiner concluded by stating "[t]hus resulting in the practice of claims 11, 22-24 and 30-31 with a reasonable expectation of success."

The Examiner then asserted that for claims 25-29, Bar-Tana teaches that the daily dosage of the compound of formula (I) will depend on the age, needs, and tolerance of the individual patient.

The Examiner further asserted that at the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to further optimize the dose regimen based on age, tolerance, and the individual needs of the patient as taught by Bar-Tana, thus resulting in the practice of claims 25-29 with a reasonable expectation of success.

Applicants' Response

In response, applicants respectfully traverse the rejection. However, for the purpose of expediting prosecution and without conceding the correctness of the Examiner's position, applicants have herein amended claim 11 to recite "a range from about 100 mg per day to about 400 mg per day." The use of this specific dosage range of M16 for treating dyslipoproteinemia and more particularly the optimal effects associated with this dosage range would not have been rendered obvious by the disclosure of Bar-Tana.

Bar-Tana does not teach that optimal treatment of different component diseases of Syndrome X requires different dosages of M16

Bar-Tana discloses that *Psamomys Obesus* (not humans) were fed "Amrod 935" Purina Chow diet supplemented with 0.1% of M16. See, Bar-Tana, column 20, lines 66-68. Table VI of Bar-Tana discloses that serum triglycerides and serum cholesterol levels were reduced in animals fed the M16 supplemented diet. Bar-Tana further discloses that feeding diabetic *Psamomys Obesus* a diet supplemented with 0.1% M16 resulted in correction of the animals' glucose tolerance test curves. See, Bar-Tana, columns 21-22, Experiment II(c) and Table VIII. Moreover, the M16 supplemented diet lowered serum insulin levels in the diabetic animals. See, Bar-Tana, column 22, lines 13-16. Importantly, Bar-Tana does not disclose any data showing the effect of M16 administration at different doses.

Thus, one of ordinary skill in the art at the time of applicants' invention would not have expected that any specific dosage of M16 effective to treat one component disease of Syndrome X in a human would not be equally effective in treating other component diseases of Syndrome X. Consequently, one of ordinary skill in the art could not have predicted what dosages of M16 would be optimal for treating dyslipoproteinemia.

The January 6, 2011 Declaration of Dr. Jacob Bar-Tana shows that the claimed dosage range produces an unexpected result relative to the treatment of dyslipoproteinemia

The previously submitted Declaration of Dr. Jacob Bar-Tana establishes that the maximal effective dose for reducing elevated

triglycerides is 200 mg/day. For the Examiner's convenience, a copy of the Declaration submitted with the Amendment filed January 6, 2011 is attached hereto as **Exhibit A**. Specifically, doses of 30-200 mg/day decreased triglycerides by 42-53% from baseline, while dose escalation to 400 mg/day provided essentially the same decrease and did not produce any further significant decrease. See, Declaration, page 3 and Table 1.

In contrast, the data in Table 2 of the Declaration shows that a 200 mg/day dose of M16 (the maximal effective dose for lowering triglycerides) resulted in an insignificant increase in sensitization to insulin. See, page 5 and Table 2 of the Declaration. [1]

This result could not have been predicted from the teachings of Bar-Tana because Bar-Tana does not suggest a maximally effective dose for treating Syndrome X in a human, let alone a maximally effective dose of M16 for treating dyslipoproteinemia, a specific component disease of Syndrome X. As noted above, Bar-Tana discloses feeding M16 to *Psamomys Obesus* at a single concentration which was sufficient to reduce serum triglyceride, serum cholesterol, and serum insulin levels, and to correct glucose tolerance test curves. Consequently, applicants' results which show that a different dosage of M16 is required to maximally treat different component diseases of Syndrome X in a human, in this case dyslipoproteinemia, is unexpected.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a) in view of the unexpected result obtained when treating dyslipoproteinemia using applicants' claimed dosage range.

---

1 Tables 1 and 2 of the Declaration show data for the same six subjects who received the 200 mg/day dose of M16.